



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,568	09/15/2003	Steven Z. Wu	50623.335	2840

7590 08/06/2009
Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
One Maritime Plaza
San Francisco, CA 94111-3492

EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
----------	--------------

1615

MAIL DATE	DELIVERY MODE
-----------	---------------

08/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/663,568	Applicant(s) WU ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 July 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: _____.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement(s)*. (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Humera N. Sheikh/
 Primary Examiner, Art Unit 1615

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues that the "Examiner fails to give a rational reason as to why one would incorporate an encapsulated drug of Hunter in the multi-structure of Wang". It is the position of the Examiner that one of ordinary skill in the art seeking to find a therapeutic device that can be formulated both with and without an active substance would turn to the teachings of Wang. The secondary reference of Wong amply demonstrates the use of devices, such as stents, that can contain drug as well as be devoid of any drug. One would be motivated to do so based on the beneficial results achieved by Wang. Applicant's argument that "having a coating layer that is free from any therapeutic substances is important because it allows for greater control of the release of the loaded microparticles containing the therapeutic substance" is noted. This argument was not convincing since the claims are silent in terms of this feature (i.e., drug release control). Thus, Applicant's arguments do not establish the scope of claims being presented. See *In re Van Geuns*. Further, these properties (drug release control) would also be permissible given the devices of Wang, since Wang also teaches devices devoid of active agent. The argument that "Wang does not demonstrate a finite number of identified predictable solutions and that there are many drug, polymer and drug-polymer layer combinations taught by Wang and no direction as to which of the choices is likely to be successful" was not deemed persuasive. The reference is clearly suggestive of the use of therapeutic devices (stents) whereby the device has a coating layer free from active substance. Since this element is taught in the prior art, it sufficiently renders the instant claims *prima facie* obvious. Further, it is of no moment that Wang discloses various types of polymers/coatings, since the reference is vividly indicative of therapeutic devices which are free of active agent, as is desired by Applicant. Further for the reasons advanced in the Final Office Action dated 5/22/09, Applicant's arguments were not held persuasive.